

Docket No.: CI-0004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

David M. MANN, Wilson BURGESS, William N.
DROHAN, Yuri GRIKO and Martin J. MACPHEE

Group Art Unit: 1614

Serial No.: 09/942,938

Filed: August 31, 2001

Confirm. No.: 8959

For: METHODS FOR STERILIZING PREPARATIONS OF DIGESTIVE ENZYMES

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the indicated date. Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, that information cited in the statement is considered to be and/or is material to patentability, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. §120. 1138 OG 37, 38 (May 19, 1992).

— 1. This Information Disclosure Statement is being filed (i) within three months of the U.S. filing date of a U.S. application other than a CPA continued prosecution application under §1.53(d) OR (ii) within three months of the date of entry of the national stage as set forth in §1.491 in an international application OR (iii) before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 C.F.R. §1.97(b).

X 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application. 37 C.F.R. §1.97(c).

— a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart

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foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

— b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).

X c. Attached is our check no. 10314 in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.

— 3. This Information Disclosure Statement is being filed after the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application, but on or before payment of the Issue Fee. Attached is our check no. ____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 C.F.R. §1.97(d).

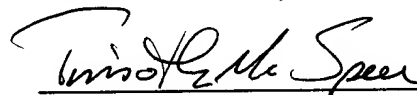
— a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

— b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).

— 4. Other.

X 5. To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

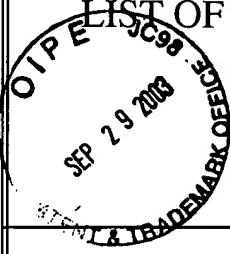
Respectfully submitted,
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DRM/TMS:dep

 <p>LIST OF PRIOR ART CITED BY APPLICANT (PTO-1449)</p>				ATTY. DOCKET NO. CI-0004		APPLN. SERIAL NO. 09/942,938	
				APPLICANT(S) David M. MANN, Wilson BURGESS, William N. DROHAN, Yuri GRIKO and Martin J. MACPHEE			
				FILING DATE August 31, 2001		GROUP 1614	
U.S. PATENT DOCUMENTS							
EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE	
	6,346,216 B1	02/12/02	KENT	422	22	05/15/00	
	6,312,931 B1	11/06/01	O'DWYER et al.	435	173.1	02/11/00	
	6,358,284 B1	03/19/02	FEARNOT et al.	623	23.72	06/02/99	
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	6,384,419 B1	05/07/02	PURTLE	250	526	03/30/00	
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	6,485,723 B1	11/26/02	BADYLAK et al.	424	93.7	05/08/00	
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	6,383,810 B2	05/07/02	FIKE et al.	435	384	02/13/98	
U.S. PATENT APPLICATION PUBLICATIONS							
	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS		
	US2002/0064807 A1	04/30/02	BADYLAK et al.	435	34	11/14/01	
	US2002/0106394 A1	08/08/02	TUCKER et al.	424	423	09/18/01	
	US2002/0188319 A1	12/12/02	MORRIS et al.	606	213	06/10/02	
	US2003/0068815 A1	04/10/03	STONE et al.	435	325	05/17/02	
	US2001/0049141 A1	12/06/01	FIKE et al.	435	384	02/13/98	
U.S. PATENT APPLICATIONS							
	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS		
FOREIGN PATENT DOCUMENTS							
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
	EP0808167 B1	06/05/02	EPO				
	EP0820301 B1	07/24/02	EPO				
	WO 00/28552	05/18/00	PCT				
OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)							
	P.V. Kapanin et al., "Feasibility of liposome cryoradiation sterilization," Khimiko-Farmatsevticheskii Zhurnal, 1988, Vol. 22(4), Abstract, pp. 479-82.						
EXAMINER				DATE CONSIDERED			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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